

Complete Summary

GUIDELINE TITLE

The vulvodynia guideline.

BIBLIOGRAPHIC SOURCE(S)

Haefner HK, Collins ME, Davis GD, Edwards L, Foster DC, Heaton Hartmann E, Kaufman RH, Lynch PJ, Margesson LJ, Moyal-Barracco M, Piper CK, Reed BD, Stewart EG, Wilkinson EJ. The vulvodynia guideline. J Lower Genital Tract Disease 2005;9(1): 40-51. [48 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Vulvodynia (vulvar pain or discomfort)

GUIDELINE CATEGORY

Diagnosis
 Evaluation
 Management
 Treatment

CLINICAL SPECIALTY

Family Practice
Obstetrics and Gynecology
Surgery

INTENDED USERS

Health Care Providers
Patients
Physical Therapists
Physicians
Psychologists/Non-physician Behavioral Health Clinicians

GUIDELINE OBJECTIVE(S)

To provide a review of the literature and make known expert opinion regarding the treatment of vulvodynia

TARGET POPULATION

Women with or suspected of having vulvodynia

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Physical evaluation and patient history
2. Cotton swab testing for pain
3. Wet prep, vaginal pH, fungal, and gram stain
4. Yeast culture

Management/Treatment

1. Vulvar care measures
2. Topical medications
 - Lidocaine ointment 5% (Xylocaine jelly 2% or ointment 5%)
 - Lidocaine 2.5% and prilocaine 2.5% (Emla)
 - Lidocaine 4% or 5% (ELA-Max, L-M-X 4, L-M-X 5)
 - Benzocaine (considered, but not recommended)
 - Diphenhydramine (considered, but not recommended)
 - Petrolatum (Vaseline)
 - Estrogen
 - Capsaicin
 - Topical nitroglycerin
 - Amitriptyline 2% (Elavil)
 - Baclofen 2% (Lioresol)
3. Oral medications
 - Antidepressants
 - Tricyclic antidepressants, including amitriptyline (Elavil), Nortriptyline (Pamelor), Desipramine (Norpramin)
 - Selective serotonin reuptake inhibitors
 - Venlafaxine (Effexor XR)

- Anticonvulsants
 - Gabapentin (Neurontin)
 - Carbamazepine (Tegretol)
 - Topiramate (Topamax)
 - Tramadol (Ultram)
4. Intralesional injections
 - Triamcinolone acetonide 0.1% and bupivacaine
 - Submucosal methylprednisolone and lidocaine
 - Interferon-alpha (IFN-alpha)
 5. Biofeedback/physical therapy (pelvis floor awareness)
 6. Complementary and alternative therapies
 7. Low oxalate diet with calcium citrate supplementation
 8. Cognitive behavioral therapy/sexual counseling
 9. Surgery
 - Total vestibulectomy
 - Local excision
 - Perineoplasty
 - Surgery for pudendal nerve entrapment

MAJOR OUTCOMES CONSIDERED

- Pain
- Symptom reduction
- Sexual functioning
- Quality of life
- Patient satisfaction

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Experts reviewed the existing literature to provide new definitions for vulvar pain and to describe treatments for this condition.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The International Society for the Study of Vulvovaginal Disease Terminology and Classification

The most recent terminology and classification of vulvar pain by the International Society for the Study of Vulvovaginal Disease (ISSVD) defines vulvodynia as "vulvar discomfort, most often described as burning pain, occurring in the absence of relevant visible findings or a specific, clinically identifiable, neurologic disorder." It is not caused by infection (candidiasis, herpes, etc.), inflammation (lichen planus, immunobullous disorder, etc.), neoplasia (Paget's disease, squamous cell carcinoma, etc.), or a neurologic disorder (herpes neuralgia, spinal nerve

compression, etc). The classification of vulvodynia is based on the site of the pain, whether it is generalized or localized, and whether it is provoked, unprovoked, or mixed.

Causes

Several causes have been proposed for vulvodynia, including embryologic abnormalities, increased urinary oxalates, genetic or immune factors, hormonal factors, inflammation, infection, and neuropathic changes. Most likely, there is not a single cause.

Diagnosis and Evaluation of the Patient with Vulvodynia

History should identify the patient's duration of pain, previous treatments, allergies, past medical and surgical history, and sexual history. The sexual history is best taken when the patient is clothed and has spent some time interacting with you. Ask permission to discuss the patient's sexual life, even if permission seems implied.

Cotton swab testing (see Figure 1 of the original guideline document) is used to localize painful areas and to classify the area as painless, or having mild, moderate, or severe pain. A diagram of the pain locations is helpful to assist in assessing the pain over time. The vagina is examined and a wet prep, vaginal pH, fungal, and gram stains are performed as indicated. Fungal culture may identify resistant strains, but sensitivity testing is generally not required.

Vulvodynia Treatments

Multiple treatments have been used for vulvodynia, including vulvar care measures; topical, oral, and injectable medications; biofeedback; physical therapy; low-oxalate diet and calcium citrate supplementation; and surgery (see Figure 2 of the original guideline document for a vulvodynia treatment algorithm). Newer treatments being used include acupuncture, hypnotherapy, nitroglycerin, and botulinum toxin.

Vulvar Care Measures

Gentle care for the vulva is advised. Common suggestions include wearing cotton underwear in the daytime and none at night, avoiding vulvar irritants (perfumes, dyed toilet articles, shampoos, detergents, and douches), and use of mild soaps, with none applied to the vulva. The vulva can be cleaned gently with water and patted dry. After cleansing, an emollient without preservatives (vegetable oil or plain petrolatum) helps to hold moisture in the skin and to improve the barrier function. If menstrual pads are irritating, cotton pads may be helpful. Adequate lubrication for intercourse is recommended. Ice packs are helpful in some, but produce irritation when overused. Cool gel packs may be used. Rinsing and patting dry the vulva after urination may be helpful. Use of hair dryers should be avoided.

Topical Therapies

Refer to table 1 of the original guideline document for a list of topical medications and their associated dosages and side effects.

Different topical medications have been tried as treatments for vulvar pain. In women who have been using multiple topical medications for a prolonged period, stopping all treatments may decrease symptoms.

The most commonly prescribed topical medication is lidocaine ointment 5% (Xylocaine jelly 2% or ointment 5%; AstraZeneca Pharmaceuticals LP, Wilmington, DE), applied as required for symptoms and 30 minutes before sexual activity. Emla (eutectic mixture of local anesthesia, comprised of lidocaine 2.5% and prilocaine 2.5%; AstraZeneca Pharmaceuticals LP), ELA-Max (lidocaine 4% and 5%) L-M-X 4 (formerly ELA-Max 4% cream [lidocaine 4%]; Ferndale, Ferndale, MI), and L-M-X 5 (formerly ELA-Max Anorectal 5% cream [lidocaine 5%]; Ferndale) also are used by some patients. These may cause stinging or sensitization. Male sexual partners may experience penile numbness and should avoid oral contact.

Long-term use of overnight topical lidocaine may minimize feedback amplification of pain and may allow for healing. Patients apply a copious amount of 5% lidocaine ointment to the affected area at bedtime and place a cotton ball generously coated with the 5% lidocaine ointment on the vestibule to assure overnight contact with the area (for 8 hours or more). It is important to use caution in using excessive amounts of lidocaine, because reports on lidocaine toxicity exist. Benzocaine, the anesthetic in Vagicare (Clay-Park Laboratories, Inc. Bronx, NY) and Vagisil (Combe Inc., White Plains, NY), has a propensity to produce allergic contact dermatitis and should be avoided. Diphenhydramine (Benadryl; Warner Wellcome, Morris Plains, NJ) is present in many topical anesthetic and anti-itch preparations; this also is a common sensitizer to be avoided.

Some patients benefit symptomatically from the application of plain petrolatum (Vaseline; Cheeseborough-Ponds, Greenwich, CT). Estrogen has been used topically with variable results. A recent study showed decreased estrogen receptor expression in women with vestibulitis. Additionally, for women who are able to insert medication via the vagina, the intravaginal estrogen ring may be considered.

Capsaicin is available to treat neuropathic pain. Its usefulness is limited by its extreme irritant effects. Topical nitroglycerin has been reported temporarily to improve vulvar pain and dyspareunia; however, headache was a limiting side effect. For some patients with localized pain and vaginismus, a combination of topical amitriptyline 2% (Elavil; AstraZeneca Pharmaceuticals) and baclofen 2% (Lioresol Geigy Novartis Pharmaceuticals, East Hanover, NJ) in a water washable base has been useful for point tenderness and vaginismus. A compounding pharmacy is used to formulate these topical medications. Topical therapies not shown to benefit vulvodynia include topical corticosteroids, topical testosterone, and topical antifungal medications.

Choosing the proper vehicle for these medications is as important as choosing the proper medications or combinations. In general, creams contain more preservatives and stabilizers and often produce burning on application, whereas

ointments are usually better tolerated. Some clinicians prefer commercially available topical medications, whereas others prefer to compound the medications. It is important to have a close relationship with a compounding pharmacist who can help to determine the proper combination of ingredients. Specific instructions should be included, emphasizing the area for the medication to be applied (vulva, vestibule, vagina, etc.).

Oral Medications

A variety of oral medications are used for pain control. Table 2 of the original guideline document summarizes the various oral medications used in the treatment of vulvodynia. When new medications for pain control are added, it is important to check for drug interactions with the patient's current medication.

Antidepressants. Oral tricyclic antidepressants are a common treatment for vulvar pain. This group of drugs (e.g., amitriptyline [Elavil; AstraZeneca Pharmaceuticals]), nortriptyline [Pamelor; Novartis Pharmaceuticals Corp.], and desipramine [Norpramin; Hoechst Marion Roussel for Aventis Pharmaceuticals, Bridgewater, NJ]) has been used for generalized vulvodynia; recent reports have found it to be helpful in localized pain. Often, amitriptyline is used as a first line agent. It is started at an oral dose of 5 mg to 25 mg nightly and increased by 10 to 25 mg weekly, generally not to exceed 150 mg daily. The 5- to 10-mg dose should be used to start treatment in the elderly population or patients who show sensitivity. Tricyclic antidepressants should not be stopped suddenly, but rather weaned by 10 to 25 mg every few days. Alcohol should be limited to one drink daily. Contraception should be provided in the reproductive age group. Tricyclic medications are available as syrups so that very small doses can be used to start patients with sensitivities. This medication should not be used in patients with abnormal heart rates (for example, tachycardia) or in patients taking monoamine oxidase inhibitors. Nortriptyline and desipramine are dosed in a similar fashion. Often, the full pain relief response is not evident for even 4 or more weeks of antidepressant use. Other antidepressants have been used for pain control. The selective serotonin reuptake inhibitors have been used for women with vulvodynia, as has venlafaxine (Effexor XR; Wyeth-Ayerst Co., Philadelphia, PA).

Anticonvulsants. Gabapentin (Neurontin; Pfizer, New York, NY) and carbamazepine (Tegretol; Novartis Corporation Pharmaceuticals) have been used to treat vulvodynia. Gabapentin is begun at a dose of 300 mg orally for 3 days, then gradually is increased to a maximum of 3,600 mg total daily dosage. See Table 2 of the original guideline document for specific dosing instructions. Monitoring and dosage adjustment are required for side effects, but in most cases the drug does not need to be discontinued. In the elderly, gabapentin may cause or exacerbate gait and balance problems as well as cognitive impairment. Dosage adjustment is necessary in patients with renal insufficiency.

As with tricyclic antidepressants, allow 3 to 8 weeks for titration of gabapentin to allow development of tolerance to adverse effects. As soon as the maximum tolerated dosage is reached, allow 1 to 2 weeks of medication before giving a final assessment of pain improvement. Carbamazepine, another anticonvulsant, may be used for resistant cases. Table 2 of the original guideline document describes these, as well as other medications, used for pain control.

Biofeedback and Physical Therapy

Biofeedback and physical therapy are used in the treatment of vulvar pain, both for localized and generalized pain. These techniques are particularly helpful if there is concomitant vaginismus. Biofeedback aids in developing self-regulation strategies for confronting and reducing pain. The time required for biofeedback and the frequencies of visits will vary with each person.

Physical therapists with experience in vulvar pain may be helpful. Abnormally high muscle tone, or spasm, poor contraction and relaxation cycles, and instability within the muscular structure of the pelvic floor can be identified and relieved with specific exercises. Vulvar pain also can be related to other parts of the body, such as the back or hips, so a thorough musculoskeletal evaluation should be performed. Physical therapy also may improve intercourse frequency and may decrease pain with intercourse and gynecological examinations. Physical therapy treatment techniques include internal (vaginal and rectal) and external soft tissue mobilization and myofascial release; trigger-point pressure; visceral, urogenital, and joint manipulation; electrical stimulation; therapeutic exercises; active pelvic floor retraining; biofeedback; bladder and bowel retraining; instruction in dietary revisions; therapeutic ultrasound; and home vaginal dilation.

Intravaginal electrical stimulation of the pelvic floor muscles recently has been shown to help alleviate the pain caused by pelvic muscle spasm.

Intralesional Injections

Although topical steroids generally do not help patients with vulvodynia, trigger point steroid and bupivacaine injections have been successful for some patients with localized vulvodynia. A common regimen uses triamcinolone acetonide 0.1% and bupivacaine. No more than 40 mg of triamcinolone acetonide 0.1% should be injected monthly. Combine the steroid with bupivacaine (large area, use 0.25% bupivacaine; small area, use 0.5% bupivacaine). It is important to draw up the triamcinolone acetonide before the bupivacaine to prevent contamination of the triamcinolone. Inject the combined drugs into a specific area or as a pudendal block. Generally, patients do not tolerate more than three or four injection trials. Another regimen has been reported that uses submucosal methylprednisolone and lidocaine. Interferon-alpha (IFN-alpha) has been reported as a treatment for vestibulodynia. Long-term improvement after interferon-alpha therapy is variable. Side effects include flu-like symptoms such as fever, malaise, and myalgias.

Vestibulectomy

Surgical excision is used as the last treatment option for patients with vestibulodynia. Before vestibulectomy, patients should be evaluated for vaginismus. If present, the vaginismus should be treated before surgery, because surgery is less successful in this subgroup. Vaginal dilators as well as various forms of physical therapy are beneficial for vaginismus. Sexual counseling may enhance postoperative improvement by reducing vaginismus and poor sexual arousal, which can develop after long-standing dyspareunia.

Surgical Excision

Excision of the vulvar vestibule has met with a variety of success rates. Lower success rates most likely are to be found in studies that operate on patients with longstanding problems that have failed numerous treatments. However, despite the high success rates of vestibulectomy in various studies, most experts believe that surgery should be reserved for women with longstanding and severe localized vestibular pain after other managements have yielded inadequate pain relief.

Surgical Techniques

Surgical approaches to introital dyspareunia caused by vestibulodynia can be grouped into the broad categories of 1) local excision, 2) total vestibulectomy, and 3) perineoplasty. Vestibuloplasty, a surgical procedure aimed at denervation of the vestibule without excision of the painful tissue, has been shown to be ineffective.

Local Excision. This technique requires precise localization of small painful areas outlined with a marking pen at surgery. The tissue is excised shallowly and is closed in an elliptical fashion. It may be necessary to undermine the margins for wound closure.

Total Vestibulectomy. The traditional vestibulectomy is an outpatient procedure most often performed under spinal or general anesthesia. The patient should undergo testing with a cotton swab before anesthesia while in the operating room to outline the areas of pain. Often, pain may be present throughout the vestibule. The incision may need to approach the periurethral area and to extend from the openings of Skene's ducts to the perineum. The incision is carried down laterally along Hart's line to the superior portion of the perineum. The incision should extend above the hymeneal ring. The skin, mucous membrane, hymen, and adjacent tissue are removed, excising the minor vestibular glands and transecting Bartholin's ducts. It is rare to see a cyst develop after vestibulectomy. Figure 3 of the original guideline document illustrates sharp dissection of vestibule. The vagina is undermined, mobilized, and brought down to cover the defect, which is closed in two layers using absorbable 3-0 and 4-0 sutures.

Perineoplasty. In the perineoplasty, the vestibulectomy is performed and includes removal of tissue on the perineum, usually terminating just above the anal orifice. Again, the vaginal mucosa is undermined and advanced to cover the defect.

Several studies have evaluated vulvar vestibulectomy procedures and their success rates. Complications include blood loss, wound infection or separation, granulation tissue, chronic fissuring, Bartholin's duct cyst formation, decrease in lubrication, and continued pain.

Surgery for Pudendal Nerve Entrapment. Perineal pain caused by pudendal nerve entrapment is a rare entity. The pain is exacerbated particularly by assuming a sitting position and is relieved by standing. Bowel function may be abnormal, as well as painful. When the pudendal nerve is entrapped and the patient has failed guided nerve blocks with corticosteroids, tricyclic antidepressants, anticonvulsants, and physical therapy, surgical treatment is an option. It is important to find a surgeon experienced in this area to perform the procedure when indicated.

Postoperative Care. Adequate analgesia is required during the 72 hours immediately after vestibular operations. Peri-incisional and labial injection of bupivacaine (with epinephrine in the nonclitoral areas) can reduce pain and intraoperative bleeding. Narcotics may be required for larger excisions. Local ice packs and topical lidocaine also are used. A hypnotic may be useful because the patient often is unable to sleep during the early postoperative period. The pain is maximal for 72 hours and then regresses. By 1 to 2 weeks after surgery, the patient is able to resume most activities. Intercourse should not occur until the health care provider has seen the patient for the postoperative visit and has verified adequate healing.

The vulva may be rinsed with Betadine (The Purdue Frederick Company, Norwalk, CT) or other gentle disinfectants after bowel movements. Patients should avoid constipating pain medicines if possible, should take stool softeners, and should eat bulk-forming foods. Warm sitz baths should begin after 24 to 48 hours. Vaginal dilator use may be required after surgery to minimize vestibular contraction and pain.

Complementary and Alternative Therapies for Chronic Vulvar Pain

Refer to the original guideline document for a discussion of complementary and alternative therapies for chronic vulvar pain.

Low-Oxalate Diet with Calcium Citrate Supplementation

The use of oral calcium citrate along with a low-oxalate diet is controversial but may help some women. Oxalate is an irritant, and it has been suggested that vulvar burning may be associated with elevated levels of oxalates in the urine. Evidence to support this treatment has been disputed.

Multidimensional Aspects

Sexual pain, no matter what the cause, will involve physical, psychological, and relationship aspects. Patients with localized and generalized vulvar pain need varying degrees of sexual counseling and emotional support. A comprehensive treatment approach is beneficial.

Psychological profiles of women with vulvodynia have been performed. Vulvodynia is not considered primarily a psychopathological condition. However, most patients benefit from early counseling for sexual pain. Initial counseling and education can be accomplished in conjunction with the medical appointment. This includes conducting a basic sexual functioning assessment; normalizing difficulties; offering simple suggestions regarding sexual positions, lubrication, temporary cessation of intercourse, alternatives to intercourse; and offering resource information such as reading, Web sites, and support groups. An assessment should include inquiry about relationship concerns and previous history of mental health problems, physical and sexual abuse, and substance abuse. If any of these issues are present, or if the patient is noncompliant with medical treatment, consideration for sexual counseling is recommended.

Sex therapy, couples counseling, psychotherapy, or a combination thereof, often is very helpful and in most cases will be short term. Patients need to know that referral for therapy does not mean that the clinician considers that the pain is all in the mind. Sharing a model that integrates psyche and soma can help allay fears that the patient already may have about their pain being psychological. When managing patients with vulvodynia, psychosexual and psychological issues must be considered in addition to the patients' other needs. Certified sex therapists can be found through the American Association of Sex Educators Counselors and Therapists.

Summary

Vulvar pain is a complex disorder that frequently is frustrating to both practitioner and patient. It can be a difficult process to treat. Many treatments for vulvodynia, both generalized and localized, have been discussed. It is important to recognize that rapid resolution of symptomatic vulvar pain is unusual even with appropriate therapy. Improvement in pain may take weeks to months. Also, the level of improvement needs to be addressed realistically with patients. Additionally, no single treatment is successful in all women. Concurrent emotional and psychological support can be invaluable.

CLINICAL ALGORITHM(S)

A clinical algorithm diagnosis and treatment of vulvodynia is provided in the original guideline document.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated. The guidelines are based largely on expert opinion.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis and treatment of vulvodynia

POTENTIAL HARMS

- See Table 1 of the original guideline document for a list of side effects of topical medications used to treat vulvodynia.
- See Table 2 of the original guideline document for a list of side effects of oral medications used to treat vulvodynia.
- Side effects of interferon-alpha (IFN-alpha) therapy include flu-like symptoms such as fever, malaise, and myalgias.
- Complications of vulvar vestibulectomy procedures include blood loss, wound infection or separation, granulation tissue, chronic fissuring, Bartholin's duct cyst formation, decrease in lubrication, and continued pain.

CONTRAINDICATIONS

CONTRAINDICATIONS

Tricyclic antidepressants should not be used in patients with abnormal heart rates (for example, tachycardia) or in patients taking monoamine oxidase inhibitors.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Haefner HK, Collins ME, Davis GD, Edwards L, Foster DC, Heaton Hartmann E, Kaufman RH, Lynch PJ, Margesson LJ, Moyal-Barracco M, Piper CK, Reed BD, Stewart EG, Wilkinson EJ. The vulvodynia guideline. J Lower Genital Tract Disease 2005;9(1):40-51. [48 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

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2005 Jan

GUIDELINE DEVELOPER(S)

American Society for Colposcopy and Cervical Pathology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Society of Colposcopy and Cervical Pathology

GUIDELINE COMMITTEE

Not stated

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the [Journal of Lower Genital Tract Disease Web site](#).

Print copies: Available from the American Society of Colposcopy and Cervical Pathology, 20 West Washington St., Suite 1, Hagerstown, MD 21740.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

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